

**S/N 10/821,260**

Attorney Ref. No. 6298-456

**REMARKS:**

**Remarks About the Drawings:**

Applicants gratefully acknowledge the Examiner's diligence in reviewing the specification, including the drawings, and directing Applicants' attention to the clerical error of not mentioning reference number 1 in the written description.

Applicants have now amended FIG. 2 by changing reference number "1" to reference number -- 19 --, which is mentioned in the Specification, for example at page 5, line 31. Applicants respectfully request entry of the enclosed Drawing Amendment effecting this change.

**Remarks About the Rejections Under 35 USC 112(2):**

The Examiner has rejected claim 5 under 35 USC 112(2) as being indefinite. Without admitting that claim 5 is indefinite, Applicants have cancelled claim 5, as well as claims 18 and 56, in order to expedite the prosecution of this application. Accordingly, the Examiner's rejection has been overcome and notice to that effect is earnestly solicited.

**Remarks About the Prior Art Rejections:**

The Examiner has rejected claims 1, 2, 6-8 and 41-46 under 35 USC 102 as being anticipated by an article entitled "Conductive Plastics for Medical Applications" authored by Larry Rupprecht and Connie Hawkinson (hereinafter "Rupprecht et al."). The Examiner has rejected claims 3 and 4 under 35 USC 103 as being made obvious over Rupprecht et al. in view of U.S. Patent No. 6,345,617 to

**S/N 10/821,260**

Attorney Ref. No. 6298-456

Englebreth et al. Finally, as best as Applicant can understand the rejection, the Examiner has rejected claims 1, 2, 5-8 and 41-46 as being made obvious over Rupprecht et al. in view of various RTP compound product sheets cited by Applicants. Applicants respectfully submit that the claims are allowable over the cited references for at least the following reasons.

First, independent claim 1 recites “an antistatic holding chamber.” Independent claim 41 has been amended to recite a similar limitation. Claim 46 has been rewritten in independent form as claim 45, which now recites that “said antistatic component is selected from the group consisting of a holding chamber, a mouthpiece and a backpiece.” After amendment, previously withdrawn claims 9-13, 14-17, 19-21, 47-51, 53-55, 57 and 58 now read on the elected species directed to the antistatic holding chamber. Accordingly, Applicants have provided those claims with the proper indicators showing the current status thereof.

As set forth in Applicants specification, a “holding chamber” is configured to receive a medicament from a separate dispensing device, such as a pressurized metered dose inhaler (Specification at 4, line 27 to 6, line 9). The “holding chamber can also be used in conjunction with medication delivery containers other than a pMDI container, including for example and without limitation nasal sprayers, dry powder inhalers and nebulizer systems” (Specification at 5, lines 16-19). “In all of the embodiments, the chamber housing 4, 20, 70 defines an interior space 19, 56, 82

**S/N 10/821,260**

Attorney Ref. No. 6298-456

and further includes an output end 14, 58, 84, 94, through which the medication is dispensed to the user” (Specification at 5, line 30 to 6, line 1).

Under 35 USC 102, all of the limitations of a claim must be found, expressly or inherently, in a single reference. Contrary to the Examiner’s assertions (Office Action at 3-4), Rupprecht et al. does *not* disclose incorporating an antistatic material into a “holding chamber.” Rather, as acknowledged by the Examiner (Office Action at 4), Rupprecht et al. only discloses using a “Polycarbonate (and Polycarbonate Blends)” material for “equipment housings and reservoirs,” and using a “Polysulfone (PSO)” material for “respirators [and] nebulizers.” While nebulizer *systems* and respirator *circuits* *may* incorporate a holding chamber (Specification at 5, lines 19-22), a nebulizer and/or a respirator does not require such a device. Accordingly, the simple disclosure of such devices in Rupprecht et al. does not disclose a “holding chamber,” expressly or inherently.

Likewise, the recitation in Rupprecht of “equipment housings and reservoirs” does not disclose a “holding chamber,” expressly or inherently. Indeed, a holding chamber does not provide a housing or reservoir for any type of “equipment.” Finally, Rupprecht et al. also does not disclose, expressly or inherently, a mouthpiece or a backpiece made of antistatic material as recited in claim 45 (formerly claim 46).

For these reasons, the Examiner has not carried his burden in showing that Rupprecht et al. anticipates claims 1, 41 and 45.

With respect to the rejection of claims 1, 41 and 45 under 35 USC 103 over Rupprecht et al and the RTP references, Applicants note that the Examiner has not cited the RTP references as disclosing or suggesting a holding chamber, or for that matter a mouthpiece or backpiece, as recited in claims 1, 41 and 45. Accordingly, the RTP references do not supply any of the deficiencies of the Rupprecht et al reference in that regard, and even if combined, those references fail to disclose or suggest all of the limitations of the noted claims. Accordingly, the Examiner has failed to make out a prima facie case of obviousness with respect to those references (see MPEP 2143.03 – all limitations must be disclosed for prima facie showing of obviousness).

While Applicants believe the claims, including the dependent claims, are further patentable over Rupprecht et al. for various reasons, Applicants hereby make further comment about only a few of those claims in order to simplify this response. Such comment is made without prejudice as to additional arguments that can be made concerning those claims or any other claim.

In particular, claim 7 recites that “at least a portion of said holding chamber is see-through.” Likewise, claim 41 recites “an antistatic holding chamber comprising a see-through material having a surface resistivity of less than about  $10^{12}$  ohm/sq,” and claim 21 recites that “at least a portion of said holding chamber and said second antistatic component is see-through.”

While Rupprecht et al. admittedly discloses that Polysulfone (PSO) can be supplied in transparent grades, the chart at page 6, line 2 of Rupprecht et al. does not

**S/N 10/821,260**

Attorney Ref. No. 6298-456

disclose that PSO is available in antistatic grades of 10E10 and about 10E12 ohm/sq (box not checked). Moreover, there is no suggestion that such a material would be suited for use as a holding chamber, let alone as a mouthpiece or backpiece.

Moreover, the citation in Rupprecht et al at page 9, wherein it is stated that “a number of conductive thermoplastic compounds retain transparency while exhibiting static-control properties,” actually teaches away from Applicants invention when the reference is considered in its entirety. In particular, Rupprecht et al. discloses that “contact clarity – the ability to read objects through a directly contacting plastic material – is a desirable property that can be achieved in packaging applications, enabling bar code imprints or laser markings to be accurately detected and read by automatic equipment,” and further that “contents of packages can also be identified by color coding, without violating the package seal” (Rupprecht et al. at 9).

In contrast, the holding chamber, or other antistatic component, of Applicants’ invention is not used as a packaging component or application, and there is no reason for the user to be able to read through the material as disclosed in Rupprecht et al. Rather, the plastic material of Applicants invention “can be made see-through, such that the user or caretaker can monitor and visualize the interior of the holding chamber and/or component,” for example to check for foreign objects or to monitor the flow of medicament (Specification at 3, lines 15-18).

Accordingly, Rupprecht et al. does not disclose or suggest making a holding chamber, or mouthpiece or backpiece, see-through. Moreover, as noted above, the RTP

**S/N 10/821,260**

Attorney Ref. No. 6298-456

references do not supply any of the deficiencies of Rupprecht et al. in this regard, and the noted claims should be passed to allowance for at least this additional reason.

If this case is not considered in condition for allowance, and an interview would be helpful to resolve any questions the Examiner may have, Applicants respectfully invite the Examiner to contact the undersigned attorney at (312) 321-4713.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "A. Stover", is written over a horizontal line.

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